

EXHIBIT X

From: [Freeman, Kia](#)
To: [Lucia, Jamie](#); [Proctor, Wyley](#); [E. Bradley Evans](#); [Joseph A. Schouten](#); [SJAquestiveNC](#)
Cc: [Proctor, Wyley](#); [Shyavitz, Lori J.](#); [Foley, Thomas F.](#)
Subject: RE: Aquestive v BioDelivery (No. 19-cv-00505-D) / Indivior et al. v BioDelivery (No. 5:15-cv-350-D)
Date: Thursday, June 9, 2022 5:44:58 PM
Attachments: [image001.png](#)

Jamie:

In response to your inquiry below, we conferred with ARx on the documents that you listed. ARx reported the general content of the types of documents that you identified—i.e., [REDACTED]. According to ARx, those types of documents generally describe how ARx employees perform their routine day-to-day tasks. ARx also reported that all of the types of documents that you identified are proprietary to ARx.

The types of ARx documents that you identified—i.e., [REDACTED]—are not generally relevant to issues in either of the two pending cases. For example, after their own investigation, ARx reported that [REDACTED] is entitled [REDACTED]. Similarly, ARx reported that some of the particular documents that you listed do not exist. Aquestive's request for all of ARx's [REDACTED] is unduly burdensome.

If Aquestive provides a particular reason why a specific ARx document is relevant to issues in either of the two pending cases, BioDelivery is willing to reconsider whether it should be produced. ARx advised that the types of documents that you identified are not routinely provided to the FDA, but may be made available for review by special request. If the FDA does not generally require the types of documents that you identified, BioDelivery does not understand why Aquestive would need them.

Regards,
Kia



Kia Freeman | Partner
McCarter & English, LLP
265 Franklin Street | Boston, MA 02110

kfreeman@mccarter.com | www.mccarter.com | V-Card
T 617.449.6549 M 617.549.7167

Boston | East Brunswick | Hartford | Indianapolis | Miami | Newark | New York | Philadelphia | Stamford | Washington, DC |
Wilmington

From: Lucia, Jamie <jlucia@Step toe.com>
Sent: Tuesday, May 31, 2022 5:59 PM
To: Proctor, Wyley <wproctor@McCarter.com>; E. Bradley Evans <EBE@wardandsmith.com>; Joseph A. Schouten <JAS@wardandsmith.com>; SJAquestiveNC <SJAquestiveNC@Step toe.com>
Cc: Freeman, Kia <KFreeman@McCarter.com>; Shyavitz, Lori J. <LShyavitz@McCarter.com>; Foley, Thomas F. <tfoley@McCarter.com>
Subject: RE: Aquestive v BioDelivery (No. 19-cv-00505-D) / Indivior et al. v BioDelivery (No. 5:15-cv-350-D)

****External Message****

Wyley,

Following up on my email below, please let us know the status of BDSI's production of the identified documents as well as the status of BDSI's productions generally.

While we trust that BDSI has taken this time to research and collect responsive documents, please let us know by the end of this week a date certain by which such production will be made.

We are looking forward to your prompt response.

Regards,
Jamie

Jamie L Lucia
Partner
[Pronouns](#): she/her/hers
jlucia@Steptoe.com
+1 415 365 6711 direct | +1 415 365 6700 fax

Steptoe
Steptoe & Johnson LLP
One Market Plaza | Spear Tower, Suite 3900
San Francisco, California 94105
www.steptoe.com

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From: Lucia, Jamie <jlucia@Steptoe.com>
Sent: Wednesday, March 16, 2022 4:13 PM
To: Proctor, Wyley <wproctor@McCarter.com>; E. Bradley Evans <EBE@wardandsmith.com>; Joseph A. Schouten <JAS@wardandsmith.com>; SJAquestiveNC <SJAquestiveNC@Steptoe.com>
Cc: Freeman, Kia <KFreeman@McCarter.com>; Shyavitz, Lori J. <LShyavitz@McCarter.com>; Foley, Thomas F. <tfoley@McCarter.com>
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Wyley,

We write to follow up on both our Friday call and the below email regarding the contents of Section 3 of BDSI's NDAs.

As discussed during the Friday call, below is a non-exhaustive list of exemplary SOPs and similar documents (i.e., [REDACTED] [REDACTED] that are identifiable from the face of the batch records BDSI produced.

[REDACTED]

[REDACTED]

As mentioned on the call, it is very difficult, if not impossible, for Aquestive to determine the full scope and relevancy of these various technical documents. Aquestive is similarly unable to identify whether there are other similar documents in BDSI's possession, custody, or control that are responsive to Aquestive's requests. We are providing this exemplary list in an effort to keep the dialogue open between the parties, but Aquestive maintains its position (as stated on Friday) that it is BDSI's burden to identify, collect, and produce the relevant documents responsive to Aquestive's requests. Based on the context in the batch records and the number of documents we have been able to identify that have not yet been produced, Aquestive has a good faith basis to believe that these exemplary documents are responsive to Aquestive's requests related to manufacturing, testing, and quality of the accused products, and should have already been produced. Following BDSI's suggestion during Friday's call that these documents likely were already produced, we also checked BDSI's production to ensure that we were not seeking documents that were previously produced. We were unable to locate them in any of BDSI's productions, including in the NDA files identified in the email below. If we are mistaken or inadvertently overlooked any such production, please identify the documents by Bates number.

Based on the review of the specific Bates ranges provided in the email below, we were also able to identify another example set of manufacturing-related documents that have not been produced. The NDA documents refer to various underlying studies or trials that Aquestive believes to be responsive to requests relating to the manufacturing of the accused products, but have not been produced. For example, parameter optimization and/or multi-variable design of experiments related to the manufacturing processes used in developing the accused products are summarized in the NDAs, but we have been unable to find the details of these studies in BDSI's productions to date.

For example, it appears that at least three studies related to drying are mentioned in NDA 207932, having objectives of

[REDACTED]

Additionally, for example, various summaries of results from experiments are included in NDA 205637 in Tables within

Section 3 of the NDA (e.g. "[REDACTED]

The studies or trials (including any related/underlying protocols, results, etc.) referenced in the NDAs for the accused products, which identify and/or optimize parameters related to the manufacturing process, are relevant and responsive at least to the requests relating to the manufacturing of the accused products.

Please confirm that BDSI will produce the documents requested above and provide a date on which we can expect production of the requested documents. If any of the documents must instead be obtained from ARx, please let us know so that we can include those requests in a revised subpoena to ARx. Thank you again for your willingness to engage in the meet and confer process regarding these documents.

Regards,

Jamie

Jamie L Lucia

Partner

Pronouns: she/her/hers

jlucia@Steptoe.com

+1 415 365 6711 direct | +1 415 365 6700 fax

Steptoe

Steptoe & Johnson LLP

One Market Plaza | Spear Tower, Suite 3900

San Francisco, California 94105

www.steptoe.com

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From: Proctor, Wyley <wproctor@McCarter.com>

Sent: Friday, March 11, 2022 8:00 AM

To: Lucia, Jamie <jlucia@Steptoe.com>; E. Bradley Evans <EBE@wardandsmith.com>; Joseph A. Schouten <JAS@wardandsmith.com>; SJAquestiveNC <SJAquestiveNC@Steptoe.com>

Cc: Freeman, Kia <KFreeman@McCarter.com>; Shyavitz, Lori J. <LShyavitz@McCarter.com>; Foley, Thomas F. <tfoley@McCarter.com>; Proctor, Wyley <wproctor@McCarter.com>

Subject: FW: Aquestive v BioDelivery (No. 19-cv-00505-D) / Indivior et al. v BioDelivery (No. 5:15-cv-350-D)

Hi all,

Please find below an email that I genuinely believed was sent last week. It appears my memory deceived me.

Wyley

Jamie,

As we previously noted, very detailed information about the manufacturing processes, including "how" information, is provided in the batch records. Additional "how and why" information can found in the FDA submissions under Section 3 (Manufacturing Process Development) that were previously produced, examples of which were identified in BDSI's amended response to Aquestive's Interrogatory No. 2, dated February 9, 2022 (including BDSI-BEL-00885640 through BDSI-BEL-00885733 and BDSI-BEL-00002386 through BDSI-BEL-00002461).

Examples of the Section 3 Manufacturing Process Development information:

For Belbuca:

BDSI-BEL- 00002386 to BDSI-BEL- 00002461
BDSI-BEL- 00833449 to BDSI-BEL- 00833529
BDSI-BEL- 00843526 to BDSI-BEL- 00843604
BDSI-BEL- 00854498 to BDSI-BEL- 00854577
BDSI-BEL- 00860119 to BDSI-BEL- 00860201
BDSI-BEL- 00885640 to BDSI-BEL- 00885733
BDSI-BEL- 00811523 to BDSI-BEL- 00811542
BDSI-BEL- 00830897 to BDSI-BEL- 00830906

For Bunavail:

BDSI-BUN-00001085 to BDSI-BUN-00001101
BDSI-BUN-00010085 to BDSI-BUN-00010103
BDSI-BUN-00014286 to BDSI-BUN-00014303
BDSI-BUN-00015708 to BDSI-BUN-00015729
BDSI-BUN-00021118 to BDSI-BUN-00021138

Additional materials:

Document entitled "Pharmaceutical Development of Buprenorphine/Naloxone Buccal Films" BDSI-BUN-00001105 to BDSI-BUN-00001525.

We are committed to helping you navigate the COVID-19 crisis. Please visit our [Coronavirus Resource Center](#) for important updates providing business guidance throughout this pandemic. For immediate questions, please email your McCarter contact or our [COVID-19 Taskforce](#).

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